

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

Page 7

REMARKS

In the Office Action of October 7, 2009, the rejection of claims 1-29 was continued in view of Gough '143 or Gough '143 in view of Swanson.

By the Amendment new claims 30-32 are presented. Claim 30 corresponds to a main claim indicated as allowable by the EPO Appeal Board in the corresponding EP application subject to processing of formal matters in the Examining Division and with minor editing to comply with 35 U.S.C. 112, second paragraph. New claims 31 and 32 are parallel to claims 28 and 29 but depend from claim 30.

After the Office Action of October 7, 2009, the resolution of this application seems to depend on the factual issues of interpreting the scope of the teaching of the Gough et al. '143 reference.

The Office action makes certain findings on what would be obvious to one of ordinary skill in the art at the time of the invention. That time frame is approximately the year 2000 based on the priorities claimed herein. That time is only two years after the issuance of Gough et al. '143 in a time frame when applications were not published prior to issuance.

In response to these findings, a Declaration of Dr. Dieter Haemmerich, one of the co-inventors herein, is submitted to comment on the actual state of the art in the year 2000 as it relates to the present invention.

The Examiner has made findings that Gough et al. '143 describes or inherently teaches the following elements relevant to evaluating the limitations of claims 16, 28 and 29, as well as other claims in the application such as claims 1 and 30 and claims dependent thereon:

1. The Examiner cites Figs. 7 and 8 of Gough et al. '143 as showing two spaced apart electrode sets of three electrodes, one on the trocar 14 and one set on the insulating sleeve 18 (See page 3, line 4 through page 4, line 7, of the Office Action of October 7, 2009);

Applicants' response is that Fig. 8 of Gough et al. '143 only shows a vertical plane of energization provided by two electrodes in each electrode set being in the plane of the paper on which Fig. 8 is presented, and that even if there is some fringing of the energy that this does not meet the limitations of the claims of three electrodes in each set creating a plane for emitting RF energy. It further does not meet the recitation in the dependent claims wherein the three

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

Page 8

electrodes in each set have equal angular spacing as recited in various claims cited below. Fig. 7 shows only one set of three electrodes in the sleeve 18. No figure in Gough et al. shows two sets of three electrodes and such an embodiment is not specifically described in Gough et al. '143.

2. The Examiner finds that the upper end portion of the trocar in Gough et al. '143 is insulated (between the electrode sets) citing Fig. 4 and the text at col. 8, lines 1-4 (See page 6, lines 15-20 of the Office Action of October 7, 2009);

The great weight of the evidence discussed below will show that the trocar 14 is not taught as insulated along the upper end in Gough '143 patent in Fig. 4, or elsewhere in Gough '143.

3. The Examiner finds that Gough et al. '143 suggests that a bipolar power supply is connected to the antennas 16 or between the trocar 14 and the antennas 16 and this meets the claim limitations on the bipolar energization between two electrode sets of three electrodes each, found in claim 16, 28 and 29 (See page 6, lines 3-14 and lines 21-24, the Office action of October 7, 2009);

The response is that these two descriptions are not the same thing as the energization recited in the claims. The energization between the trocar 14 and the antennas 16 or between the antennas 16 is the energization of one probe having one set of electrodes or is between electrodes in an axial plane parallel to the shaft and is not therefore substantially volumetric without rotation of the shaft. The energization in the present claimed invention corresponds to the energization between two probes each having an electrode set of three electrodes each and this was not taught in Gough et al. '143 or the contemporaneous commercial embodiments of Rita Medical as explained in the Declaration of Dr. Dieter Haemmerich, submitted herewith.

4. The Examiner finds at pages 2 and 3, of the Office action, that Gough et al. '143 describes a coaxial configuration of two concentric shafts, considering the insulated sleeve 18 to be one of those shafts, and that modifying this construction to provide two concentric shafts each having has a tubular metal inner portion and an insulated outer portion would be an obvious modification (Page 2 and 3, Office action of October 7, 2009);

Applicants' response is that the modification of the sleeve-and -trocar embodiment in Gough et al. '143 to reach the claimed embodiments of two concentric shafts each having has a

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

Page 9

tubular metal inner portion and an insulated outer portion or two side-by-side shafts is essentially modifying the energizing one probe as taught in Gough et al. and the contemporaneous commercial embodiments of Rita Medical, to the energizing of two probes, and this modification was not taught or suggested by the real world contemporaneous embodiments as discussed in paragraphs 10-20 in the Declaration of Dr. Dieter Haemmerich submitted herewith.

5. The Examiner finds that although Gough does not describes a side-by-side multiple shaft configuration, that this modification to the Gough et al. teaching is obvious (Page 2, 2d paragraph of the Office action of October 7, 2009).

Applicants' response is parallel to the preceding response, that this would be a modification of energizing one probe as taught in Gough et al. '143 and the contemporaneous commercial embodiments of Rita Medical to the energizing of two probes, and this was not taught in the art as discussed in paras. 10-20 in the Declaration of D. Haemmerich submitted herewith.

6. The Examiner finds that the predetermined spacing between the electrode sets is obvious when viewing Gough et al. '143, Fig. 8 (See Office Action of October 7, 2009, page 7, line 11 through page 8, line 6.)

Applicants' response is that there is no teaching in Gough et al. '143 of kits with spacings for different sizes of tumors or presetting the spacing of the electrodes before handling of the device by a physician.

A *prima facie* case of obviousness is made by finding each and every limitation of the claims in the prior art. Applicant's understanding of the law of obviousness, even post-KSR, is that claim limitations cannot be presumed to make a *prima facie* case, simply by citing the level of skill of a person of ordinary skill in the art. Therefore, it appears that a *prima facie* case not been made out as to one or more of the above features of the claims.

MPEP 2143.01 Section IV provides the following guidance in this area: A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

Page 10

combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). " [R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR, infra*, 550 U.S. at 412, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)

The reliance on the level of skill in the art without support in documentary evidence is carefully limited by MPEP 2144.03. Many of the Examiner's findings are unclear as to whether the Examiner is relying on disclosure in Gough et al. '143 to meet a specific claim limitation or whether the Examiner is relying on the skill of one of ordinary skill in the art to make a modification to what is shown in Gough et al. 143.

In either case, it is believed that the following features are not expressly found in Gough et al. '143 and that the modification of what is found in Gough et al. '143 was not obvious to one of ordinary skill in the art in the year 2000.

1. Gough et al. '143 does not show or suggest two sets of three electrodes defining two respective axially spaced apart planes as claimed in claim 1, paras. (c) and (d), claim 16, paras. (b) and (c) and claim 30, lines 5-10.
2. Gough et al. '143 does not teach connecting a bipolar power supply between the two sets of three electrodes each (as defined in feature no. 1), and as claimed in claim 1, para. (e), claim 16, para (d) and claim 30, lines 11-12.
3. Gough et al. '143 does not show or suggest the insulation of a support shaft between two electrode sets of three electrodes each as claimed in claim 1, para. (f), claim 16, para. following para. (d) and claim 30, last three lines.
4. Gough et al. '143 does not show or suggest a shaft configuration with coaxial shafts in which each shaft is tubular metal with an insulated outer surface as claimed in claims 28 and 31.
5. Gough et al. '143 does not show or suggest a shaft configuration with two side-by-side shafts as claimed in claims 29 and 32.
6. Gough et al. '143 does not show or suggest providing a shaft configuration with a two electrode sets of three electrodes having a predetermined axial offset prior to placement in a patient as claimed in claim 1, para. (c), claim 16 para. (c), para. 30, line 7, and claim 32.

If the Examiner's assumptions concerning the Gough '143 teachings are not correct in any substantial way, and these features are not found in the Gough et al. '143 reference, then the gap between what it taught in the reference and *a prima facie* case is so great that the invention of the claims cannot be considered obvious under 35 U.S.C. 103(a). In fact, none of the six differences from the prior art cited herein is found in Gough et al. '143.

For example, if features, 1, 2, 3, 4 and 6 are not found in Gough et al. '143, then the chances of one modifying the Gough et al. reference to add five features in various combinations to construct embodiments and test them to reach the claimed invention in the year 2000 is not foreseeable or predictable under *KSR International Co. v. Teleflex Inc., et al.*. 550 U.S. 398, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385.

Similarly, if features 1, 2, 3, 5 and 6 are not found in Gough et al. '143, then the chances of one modifying the Gough et al. reference to add five features in various combinations to construct embodiments and test them to reach the claimed invention in the year 2000 is not foreseeable or predictable under *KSR International Co. v. Teleflex Inc., et al., supra*.

Factual Issue No. 1: Are the two sets of radially extensible three electrodes to define respective, axially spaced apart planes disclosed or suggested in Gough et al. '143, Fig. 8?

The Examiner seems to rely principally on Fig. 8, as discussed at page 8, lines 6-15 of the Office action. The theory is that although only two electrodes are shown toward the top of the shaft 14 and two electrodes are shown at the top of the insulation sleeve 18, that there would be some energy that would be generated outside of a strictly axial plane represented by the paper on which Fig. 8 is illustrated. Note that shaft 14 is clearly uninsulated in this Figure, as in Fig. 6B.

In reply, it is noted that the independent claims 1, 16 and 30 all call for three electrodes radially extensible from the shaft to provide a defined plane surrounding the shaft and not simply providing some energy diverging from the shaft.

In addition, dependent claims 7, 8 and 22, specifically recite an equal angular spacing of the three electrodes in each set.

In the description of Fig. 8, at col. 8, lines 31-41, the description is incomplete in not describing the pattern of ablation and not describing how the antennas are energized. The fact that the antennas are shown differently in Fig. 8 than the other figures, does not make their

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

Page 12

resulting pattern of ablation or their manner of energization obvious beyond an axial energization in a vertical plane.

If a volumetric pattern of ablation of any significance would be created in Fig. 8, this would be done in the same manner as Fig. 5, by rotating the shaft 14.

Factual Issue No. 2: Does a bipolar power supply connected between the antennas 16 in one electrode set or between the trocar 14 and the antennas 16 in one electrode set in Gough et al. '143 meet or suggest the recitation of a bipolar power applied between two electrode sets of three electrodes each as recited in claims 1, 16 and 30?

Answer: No. To see how Gough et al. '143 energizes between trocar 14 and antennas 16, Applicants cite Gough et al. '847 cited in Applicant's Information Disclosure Statement of June 10, 2002, in the parent application No. 10/167,681, previously examined by the Examiner herein.

At col. 4, lines 41-42, Gough et al. '847 identifies element 14 as a primary antenna, not a trocar as in Gough et al. '143, col. 4, lines 43-44 and further states at lines 54-56 that antenna element 14 delivers electromagnetic energy to the tissue mass. Gough et al. '143 is consistent with this at col. 8, line 11 where it states that energization can take place between the antenna 16 and the trocar 14. At col. 3, lines 34-35, Gough et al. '143 states that the trocar becomes at least partially an antenna.

As related by Dr. Haemmerich in the Declaration accompanying this reply, in paras. 15 and 16:

"15. I have also reviewed the Gough et al., U.S. Pat. No. 5,728,143, and particularly col. 7, lines 21-30, which reads as follows:

As illustrated in FIG. 2, trocar 14 is introduced into a selected tissue mass 28. Three or more antennas 16 are positioned within a trocar lumen as trocar 14 is introduced into and through the selected tissue mass. In various embodiments, 3, 4, 5, or 6 antennas 16 are introduced laterally through trocar 14. Subsequently, antenna distal end 16' is advanced out of aperture 26 into selected tissue mass 28. Insulation sleeves 18 are adjusted for antennas 16. RF, microwave, short wave and the like energy is delivery to antenna 16 in a monopolar mode (RF), or alternatively, multiple antenna device 12 can be operated in a bipolar mode (RF).

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

Page 13

One of ordinary skill in the art in the year 2000 would not conclude that this was referring to applying bipolar power between two electrode sets or between two probes each providing one of the two electrode sets. One of ordinary skill in the art would conclude that this power delivery was between antennas in the same electrode set or between the antennas and a grounding pad as seen in the Rita Model 30 probe diagrammed above. Dr. Haemmerich goes on to say:

“16. I have also reviewed Gough et al., U.S. Pat. No. 5,728,143, and particularly Figs. 7 and 8, and col.7, lines 21-34 , and the remainder of the Gough et al. reference, and it is not described in a manner that would have been understandable by one of ordinary skill in the art at the time that the power supply of Fig. 9 or any other power supply, is connected between two electrode sets such as the electrode set in the insulating sleeve 18, and the electrode set in trocar 14 to apply bipolar power between two electrode sets as claimed in claims 16 and 28 set forth above.”

Factual Issue No. 3: Is the insulation of the shaft between the two sets of three electrodes recited in the claims either disclosed or suggested in Gough et al. ‘143, Fig. 4?

Applicants sincerely urge that there is no evidence in Gough et al. ‘143 to support the notion that the trocar 14 is insulated in Fig. 4, other than by insulating sleeve 18, which sleeve 14 is not shown in Fig. 4, but is shown in other figures.

The only insulation mentioned in the Gough et al. ‘143 patent is the insulating sleeve 18. Where mentioned or illustrated it is designated with reference number 18. In all instances, the trocar 14 is given reference number “14.” If the trocar 14 was to be insulated in one Figure and not in another Figure, other than by sleeve 18, this should have been stated in the specification, and perhaps the two trocars distinguished with different numbers. Figs. 5, 6a and 6b illustrate by the commonly known shading for metal that the upper end of the trocar is metal and not insulated.

Gough et al., U.S. Pat. No. 5,735,847 (Gough et al. ‘847) is the parent of Gough et al., U.S. Pat. No. 5,728,143 (Gough et al. ‘143). Gough et al. ‘847 was cited in Applicant’s Information Disclosure Statement of June 10, 2002 in the parent application, No. 10/167,681,

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

Page 14

and is therefore of record in this case under MPEP 2001.06(b).

At col. 4, lines 41-42, Gough et al. '847 identifies element 14 as a primary antenna, not a trocar as in Gough et al. '143, col. 4, lines 43-44 and further states at lines 54-56 that antenna element 14 delivers electromagnetic energy to the tissue mass. Gough et al. 143 is consistent with this at col. 8, line 11 where it states that energization can take place between the antenna 16 and the trocar 14. At col. 3, lines 34-35, Gough et al. '143 states that the trocar becomes at least partially an antenna.

Gough et al. '847, col. 8, lines 64-67 states:

"In FIG. 4, three secondary antennas 16 are introduced into selected tissue mass 28. The effect is the creation of an ablation volume without leaving non-ablated areas between antenna ablation surfaces. The ablation is complete."

This was modified in Gough '147, col. 8, lines 1-4 to say that "In FIG. 4, three antennas 16 are introduced into selected tissue mass 28. The effect is the creation of a substantially complete ablation volume formed between antennas 16 with a minimal central core that is not ablated." Please note the word "minimal."

The change in the description between Gough '847 and Gough '147 was simply a qualification representing some uncertainty concerning the operation of the device, it does not mean that the trocar 14 had to be insulated to achieve this result.

As related by Dr. Haemmerich in the Declaration accompanying this reply, in para. 18:

"18. Referring now to the first finding in paragraph 17 above, in reviewing Gough et al (' 143), all instances of reference number 14 refer to a trocar that is uninsulated at its upper end as shown in the cross section in Fig. 6c. When an insulating sleeve is added, it always has reference number 18. This is consistent with the known construction of the Rita Model 30 in the year 2000 as shown above in Fig. 1. It cannot be concluded that the upper end of trocar 14 in Fig. 4 is insulated from the descriptions of the embodiment of Fig. 4, particularly col. 8, lines 1-4. In fact, it would not be possible to obtain the heating zone shown as dashed ellipse in Fig. 4 if trocar 14 was insulated. Similarly, Fig. 8 shows a trocar without insulation 18 between the upper and lower antennas, and there is nothing suggesting existence of such insulation."

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

Page 15

Factual Issue No. 4: Does Gough et al. '143 disclose or suggest a shaft configuration with two coaxial support shafts where each shaft has a tubular metal inner portion and an insulated outer portion?

No, the Office action cites a sleeve 18 as the second shaft. Neither the shaft 14 nor the sleeve 18 in Gough et al. '143 literally meet the recitations in the claims of each shaft having a tubular metal inner portion and an insulated outer portion. The larger significance of this is that the Rita Medical probes which were the result of the Gough et al. '143 invention were intended to be used one at a time, whereas the invention is the first to use two such probes. Even Gough et al. '143 Figs. 7 and 8, is using but one probe. By "probe" is meant an assembly with a tubular shaft, an insulating sleeve and an electrode set of three electrodes.

Two reasons given for the rejection of claims 28 and 29 on page of the Office action are not seen to be correct, as a matter of law, even before a consideration of Gough et al. '143.

The issue of "criticality" cited at page 2 of the Office Action in rejecting claims 28 and 29 is not seen to relate to combination claims in the electrical-mechanical arts unless a range or dimension is at issue, and an item of prior art has been cited with an overlapping range to make a *prima facie* case. MPEP 2144.05

The issue of "unexpected results" cited at page 2 of the Office Action in rejecting claims 28 and 29 is legally speaking, a secondary consideration concerning nonobviousness, only after a *prima facie* case has been made out.

Factual Issue No. 5: Does Gough et al. '143 disclose or suggest a shaft configuration with two side-by-side support shafts?

No, the Office action cites a sleeve 18 as the second shaft. The second shaft is coaxial so it cannot be side-by-side and does not meet the claim limitations in claims 29 and 32.

Two reasons given for the rejection of claims 28 and 29 on page of the Office action are not seen to be correct, as a matter of law, even before a consideration of Gough et al. '143.

The issue of "criticality" cited at page 2 of the Office Action in rejecting claims 28 and 29 is not seen to relate to combination claims in the electrical-mechanical arts unless a range or dimension is at issue, and an item of prior art has been cited with an overlapping range to make a

prima facie case. MPEP 2144.05

The issue of “unexpected results” cited at page 2 of the Office Action in rejecting claims 28 and 29 is legally speaking, a secondary consideration concerning nonobviousness, only after a *prima facie* case has been made out.

Factual Issue No. 6: Does Gough et al. ‘143 show or suggest providing a shaft configuration with a two electrode sets of three electrodes having a predetermined axial offset, either in a kit or otherwise, prior to placement in a patient?

From the discussion at page 8, Examiner misunderstands the predetermined spacing issue between the electrode sets is obvious when viewing Gough et al., Fig. 8 (See Office Action of October 7, 2009, page 7, line 11 through page 8, line 6.)

The Examiner states:

“To assert that one of ordinary skill in the art, as described above, would be content to randomly position the antenna, rather than deliberately position them in a predetermined manner, so as to be sure to ablate the totality of the tumor while sparing as much healthy tissue as possible strains the bounds of credibility.”

The predetermined spacing is the result of the two electrode sets being provided with a predetermined spacing to treat different sizes of tumors. The spacing is set at the factory, not by the physician. The physician chooses a kit size or perhaps two kit sizes based on knowledge of the size of the tumor. Gough et al. ‘143 talks about manipulation, including rotation which is an *in situ* manipulation. There is no disclosure of any predetermined spacings in Gough et al. ‘143, such as to provide different sized devices, or kits for different size tumors. Gough et al. ‘143 describes physician manipulation to achieve volumetric ablation as has been discussed throughout the prosecution. The passage quoted above from the Office action misunderstands that even with predetermined spacings, a placement by the physician is still required, but not as much manipulation is required as if no predetermined spacings were provided. The claimed invention provides a more developed tool than was known from Gough et al. ‘143 or the Rita Model 30 probe discussed in paragraphs 10-20 of the Declaration of Dr. Haemmerich.

Reply to Office Action of October 7, 2009

U.S. Appl. No. 10/796,239

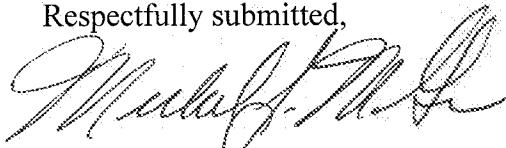
Page 17

SUMMARY

A fee for extra claims is submitted herewith. If any other fees are deemed to be due, please charge Boyle Fredrickson S.C. Deposit Account No. 50-1170.

In view of the Amendment and Remarks, reconsideration of the application is respectfully requested. After the amendment, claims 1-9, 13, and 16-22 and 28-32 are still pending, and a Notice of Allowance for these claims or an indication of allowable subject matter is earnestly solicited.

Respectfully submitted,



Michael J. McGovern
Registration No. 28,326
BOYLE FREDRICKSON, S.C.
(Customer No. 23598)
840 North Plankinton Avenue
Milwaukee, WI 53203
Telephone: (414) 225-6317